

REMARKS

Claims 11, 13-19, 21, 23-33, and 35-46 have been amended to recite a punctal plug instead of an ocular implant. Support for the amendments to the claims may be found throughout the as-filed specification. No new matter has been added. Claim 22 has been cancelled without disclaimer of the subject matter contained therein or prejudice to Applicant's right to file any continuation application directed thereto. Upon entry of this amendment, claims 11, 13-19, 21, 23-33, and 35-46 remain pending, with claims 13, 16, 18, 19, 23-28, 32, 35, and 36 withdrawn from consideration at this time.

As an initial matter, Applicant respectfully requests that the Examiner contact Applicant's representative, the undersigned below, prior to issuing the next Office Action on the merits to schedule an in-person interview with Applicant's representative.

In the Office Action dated August 25, 2010, claim 22 was rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Although Applicant respectfully traverses this rejection for at least the reasons already of record, claim 22 has been cancelled to further prosecution. Accordingly, Applicant respectfully requests that the rejection of claim 22 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 30, 31, 34, 37, and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by Ness (U.S. Patent No. 3,828,777). Applicant respectfully traverses this rejection.

As amended, claim 11 recites a punctal plug that includes "an implant body extending from a proximal end portion, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion, configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted, the entire implant body comprising a porous or absorbent material; and an active agent disposed entirely throughout the porous or absorbent material so that the entire implant body is saturated with the active agent, the active agent deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system via an exterior

surface portion of the implant body.” Applicant respectfully submits that Ness does not disclose, teach, or suggest the combination of features recited by claim 11.

Ness discloses an ocular device that includes a body that is “of a shape which is adapted for insertion and retention in the sac of the eye bounded by the surfaces of the bulbar conjunctiva of the sclera of the eyeball and the palpebral conjunctiva of the eye lid.” Ness at abstract (emphasis added). Figures 1 and 2 of Ness illustrate the ocular device in the form of an ocular insert 12 in its operative position in the lower sac 11 of the eye. See Ness at FIGs. 1 and 2 and col. 3, lines 28-46. The ocular insert of Ness is not a punctal plug and does not include an implant body that extends from a proximal end portion, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion, configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted, as recited by claim 11.

Contrary to the assertion made in the Office Action at page 4, lines 9-11, the ocular insert of Ness is not shaped and dimensioned to be inserted through the lacrimal punctum into a lacrimal canaliculus, as recited by claim 11. Ness teaches that the ocular insert disclosed therein “can be fabricated in any convenient shape for comfortable retention in the sac of the eye” and that the “marginal outline of the ocular insert can be ellipsoid, donut-shape, bean-shape, banana-shape, circular, rectangular” and that in cross-section, it can be “doubly convex, concavoconvex, rectangular, etc., as the ocular insert will tend to conform to the configuration of the eye.” See Ness at col. 7, lines 20-28 (emphasis added). None of these shapes is suitable for insertion through the lacrimal punctum and into the lacrimal canaliculus, which have substantially circular cross-sections.

In view of the foregoing, Applicant respectfully submits that claim 11 and the claims that depend from claim 11, and include additional advantageous features, are patentable over Ness, and respectfully requests that the rejection of claims 11, 15, 17, 21, and 37 be withdrawn.

Claim 30 recites a punctal plug that includes “an implant body sized and shaped for at least partial insertion into a lacrimal canaliculus, the entire implant body comprising a porous or absorbent material; and the porous or absorbent material being saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent

deliverable to tissue at or near one or both of an eye or a nasolacrimal system.” Applicant respectfully submits that Ness does not disclose, teach, or suggest all of the features recited by claim 30.

As discussed above, Ness discloses an ocular device for insertion and retention in the sac of the eye bounded by the surfaces of the bulbar conjunctiva of the sclera of the eyeball and the palpebral conjunctiva of the eye lid. The device of Ness is not a punctal plug that has an implant body that is sized and shaped for at least partial insertion into a lacrimal canaliculus, as recited by claim 30. As such, Ness does not disclose, teach, or suggest a punctal plug having the combination of features recited by claim 30.

In view of the foregoing, Applicant respectfully submits that claim 30 and the claims that depend from claim 30, and include additional advantageous features, are patentable over Ness, and respectfully requests that the rejection of claims 30, 31, 34, and 41 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 29-31, 33, 34, and 37 were rejected under 35 U.S.C. §102(b) as being anticipated by Freeman (U.S. Patent No. 3,949,750). Applicant respectfully traverses this rejection.

Claim 11 is discussed above. Applicant respectfully submits that Freeman does not disclose, teach, or suggest the combination of features recited by claim 11, because Freeman does not disclose or teach “an active agent disposed entirely throughout the porous or absorbent material so that the entire implant body is saturated with the active agent, the active agent deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system via an exterior surface portion of the implant body,” as recited by claim 11.

The Office Action asserted that “[w]hen the device is impregnated with drug, the device will be saturated with drug.” See Office Action at page 6, lines 6-7. Applicant respectfully disagrees with this statement because impregnating a material with drug does not necessarily saturate the material with drug, and the Office Action has provided no evidence to support such an assertion. See MPEP §2112 (“To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a

given set of circumstances is not sufficient," quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added)).

In view of the foregoing, Applicant respectfully submits that claim 11 and the claims that depend from claim 11, and include additional advantageous features, are patentable over Freeman, and respectfully requests that the rejection of claims 11, 15, 17, 21, 29, and 37 be withdrawn.

Claim 30 is discussed above. Applicant respectfully submits that Freeman does not disclose, teach, or suggest the combination of features recited by claim 30, because the entire plug body of Freeman is not necessarily saturated with a drug. As such, Freeman does not disclose, teach or suggest that the entire implant body comprises a porous or absorbent material, and that the porous or absorbent material is "saturated with an active agent from a proximal end portion of the implant body, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion of the implant body, configured for insertion through the lacrimal punctum into the lacrimal canaliculus when implanted, the active agent deliverable to tissue at or near one or both of an eye or a nasolacrimal system," as recited by claim 30.

In view of the foregoing, Applicant respectfully submits that claim 30 and the claims that depend from claim 30, and include additional advantageous features, are patentable over Freeman, and respectfully requests that the rejection of claims 30, 31, 33, and 34 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 30, 31, 34, 37, and 41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ness. Applicant respectfully traverses this rejection.

As discussed above, claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Ness, because Ness does not disclose, teach, or suggest the combination of features recited by claims 11 and 30, and also the claims that depend from claims 11 and 30. Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 21, 30, 31, 34, 37, and 41 be withdrawn.

In the Office Action, claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34, 37, 38, 40-42, and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ness in view of Cohan et al. (U.S. Patent No. 6,196,993, hereinafter "Cohan"). Applicant respectfully traverses this rejection.

Claims 11 and 30, and Ness are discussed above. The Office Action relied on Ness, not Cohan, for allegedly teaching the features recited by claims 11 and 30. *See* Office Action at page 8, third paragraph. Indeed, Applicant respectfully submits that Cohan does not disclose, teach, or suggest an insert having an implant body in which the entire implant body comprises a porous or absorbent material, and "an active agent disposed entirely throughout the porous or absorbent material so that the entire implant body is saturated with the active agent, the active agent deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system via an exterior surface portion of the implant body," as recited by claim 11. By way of review, Cohan discloses an ophthalmic insert 32 that includes a reservoir 34 designed to store and release medication onto the surface of the eye 10. *See* Cohan at col. 4, lines 22-28; FIG. 3. Because neither Ness nor Cohan nor any reasonable combination of Ness and Cohan discloses, teaches, or suggests the combination of features recited by claim 11, claim 11 and the claims that depend from claim 11 are patentable over Ness in view of Cohan.

Moreover, because neither Ness nor Cohan nor any reasonable combination of Ness and Cohan discloses, teaches, or suggests "the entire implant body comprising a porous or absorbent material; and the porous or absorbent material being saturated with an active agent from a proximal end portion of the implant body," as recited by claim 30, Applicant respectfully submits that claim 30 and the claims that depend from claim 30 are patentable over Ness in view of Cohan.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 14, 15, 17, 21, 29-31, 33, 34, 37, 38, 40-42, and 44 be withdrawn.

In the Office Action, claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34, and 37-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ness in view of Cohan, and further in view of Robertson (U.S. Patent Application Publication No. 2002/0193441). Applicant respectfully traverses this rejection.

As discussed above, claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Ness in view of Cohan. Applicant respectfully submits that Robertson does not make up for the deficiencies of Ness and Cohan noted above, and the Office Action essentially conceded as much. *See* Office Action at page 8, last paragraph.

Accordingly, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Ness in view of Cohan and further in view of Robertson, and respectfully requests that the rejection of claims 11, 14, 15, 17, 21, 29-31, 33, 34, and 37-44 be withdrawn.

In the Office Action, claims 45 and 46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ness in view of Yanni et al. (International Patent Publication No. WO 00/03705, hereinafter "Yanni"). Applicant respectfully traverses this rejection.

Claim 45 depends from claim 11 and claim 46 depends from claim 30. As discussed above, claims 11 and 30 are patentable over Ness. Applicant respectfully submits that Yanni does not make up for the deficiencies of Ness, because Yanni does not disclose a punctal plug having the features recited by claims 11 and 30. Indeed Yanni is merely relied upon by the Office Action for its alleged teachings of olopatadine as an active agent.

Accordingly, Applicant respectfully submits that claims 45 and 46 are patentable over Ness in view of Yanni, and respectfully requests that the rejection of claims 45 and 46 be withdrawn

In the Office Action, claims 11, 15, 16, 21, 22, 29-31, 33, and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Bhushan (U.S. Patent Application Publication No. 2004/0137068). Applicant respectfully traverses this rejection.

As discussed above, claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman. Applicant respectfully submits that Bhushan does not make up for the deficiencies of Freeman, and the Office Action conceded as much. *See* Office Action at page 10, second full paragraph.

In view of the foregoing, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman in view of Bhushan, and respectfully requests that the rejection of claims 11, 15, 16, 21, 29-31, 33, and 34 be withdrawn.

In the Office Action, claims 11, 15, 17, 22, 29-31, 33, 34, 37, 38, 40-42, and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Cohan. Applicant respectfully traverses this rejection.

The Office Action relied on Freeman for allegedly teaching all of the features recited by claims 11 and 30. As discussed above, claims 11 and 30 are patentable over Freeman. Because neither Freeman nor Cohan nor any reasonable combination thereof discloses, teaches, or suggests the combination of features recited by claims 11 and 30 for all of the reasons already on record, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman in view of Cohan.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 29-31, 33, 34, 37, 38, 40-42, and 44 be withdrawn.

In the Office Action, claims 11, 15, 17, 21, 22, 29-31, 33, 34, and 37-44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Cohan and further in view of Robertson. Applicant respectfully traverses this rejection.

As discussed above, claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman in view of Cohan. Applicant respectfully submits that Robertson does not make up for the deficiencies of Freeman and Cohan noted above, and the Office Action essentially conceded as much. *See* Office Action at page 11, third paragraph. Therefore, Applicant respectfully submits that claims 11 and 30 and the claims that depend from claims 11 and 30 are patentable over Freeman in view of Cohan and further in view of Robertson.

Accordingly, Applicant respectfully requests that the rejection of claims 11, 15, 17, 21, 29-31, 33, 34, and 37-44 be withdrawn.

In the Office Action, claims 45 and 46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Yanni. Applicant respectfully traverses this rejection.

As discussed above, claim 45 depend from claim 11 and claim 46 depends from claim 30. Applicant notes that the discussion of Freeman on pages 11 and 12 of the Office Action does not address the feature of the implant body or the porous or absorbent material being saturated with an active agent, as recited by claims 11 and 30. As discussed above, claims 11 and 30 are patentable over Freeman, because Freeman does not disclose, teach, or suggest that the plug disclosed therein is saturated with a drug.

Applicant respectfully submits that Yanni does not make up for the deficiencies of Freeman, because Yanni does not disclose a punctal plug having the features recited by claims 11 and 30. Indeed Yanni is merely relied upon by the Office Action for its alleged teachings of olopatadine as an active agent. See Office Action at page 12, second full paragraph. Accordingly, Applicant respectfully requests that the rejection of claims 45 and 46 be withdrawn.

All rejections and objection having been addressed, it is respectfully submitted that the present application is in a condition for allowance and a Notice to that effect is earnestly solicited. If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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